

REMARKS

Applicants respectfully request reconsideration of the rejections set forth in the Office Action mailed on August 8, 2003. Claims 60-62 have been withdrawn from consideration and have been cancelled herein. Claims 83 and 84 have been added. Claims 18, 19, 65, 67, 73, 76, and 82-84 are pending. All claims have been rejected.

This amendment is to expedite prosecution and should not be construed as acquiescence in any ground of rejection. Applicants reserve the right to prosecute the originally filed claims, and any other claims supported by the specification, in the future. The comments in the Office action are now addressed in turn.

Rejections under 35 U.S.C. §112, 2nd Paragraph

Claims 74 and 77-79 been rejected under 35 U.S.C. §112, second paragraph, as allegedly being indefinite for failing to particularly point out and claim the invention. Applicants respectfully traverse this rejection.

The Office has indicated that Claim 74 appears to be a substantial duplicate of claim 18. In addition, Claims 77-79 are said to be substantial duplicates of each other as well as of claim 65. Applicants have cancelled the duplicative claims herein. Applicants apologize for any inconvenience caused to the Office by this inadvertent error.

Rejections under 35 U.S.C. §112, 1st Paragraph

Claims 80-82 have been rejected under 35 U.S.C. §112, first paragraph, as allegedly failing to comply with the written description requirement. The Office questions whether the "mesylate" salt has support in the subject application. As is readily appreciated by those of skill in the art, a mesylate salt is an acid addition salt and is formed by the addition of methanesulfonic acid to a compound having a basic site (e.g., a free amine). Support for such salts can be found in the specification at, for example, page 25, lines 20-29. Applicants respectfully request that this rejection be withdrawn.

Rejections under 35 U.S.C. §102

Claims 1, 4, 7-17, 30, 64, 68-72, and 75 have been rejected under 35 U.S.C. §102(e) as allegedly being anticipated by Baxter et al. U.S. Patent No. 6,545,005 ("Baxter"). Applicants respectfully traverse this rejection.

As repeatedly indicated by the courts, anticipation requires that all of the elements and limitations of the claim be found within a single prior art reference. There must be no difference between the claimed invention and the disclosure provided by the reference, as viewed by a person of ordinary skill in the field of the invention. (*Scripps Clinic & Research Fdn. v. Genentech, Inc.*, 927 F.2d 1565, 1576 [Fed. Cir. 1991]). Furthermore, "[t]o establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. (*In re Royka*, 490 F.2d 981, 180 USPQ 580 [CCPA 1974]).

Baxter is said to describe compounds embraced by the claimed formula with the following substituents:

- i. R₁ is substituted aryl;
- ii. One of R₂ is hydrogen while the other is alkyl;
- iii. R₃ is alkyl or substituted aryl; and
- iv. R₄ is alkyl or aralkyl.

Baxter does not teach or suggest compounds utilized in the methods claimed herein. Nor does Baxter teach or suggest that the R-isomer is preferred. Applicants request that the rejection be withdrawn.

Rejections under 35 U.S.C. § 103

Comgenex and Maybridge in view of Aono

Claims 1-4, 7-19, 30, and 63-67 have been rejected under 35 U.S.C. §103(a) as being allegedly unpatentable over Comgenex and Maybridge in view of Aono. In addition, Claims 1-4, 7-19, 30, and 63-67 have been rejected under 35 U.S.C. §103(a) as being allegedly unpatentable over Comgenex and Maybridge in view of Baxter. Applicants respectfully traverse these rejections.

More specifically, the Office has cited Comgenex and Maybridge for their listings of commercial quinazolinones. Applicants respectfully maintain that these references simply detail quinazolinones that were available for purchase. They do not teach or suggest that the compounds have any therapeutic or other utilities.

To rectify this deficiency, the Office has cited Aono for the teaching that "substituted quinazolinone compounds (as a class) can treat tumors, or cellular proliferative diseases." Applicants must respectfully disagree with the Office's interpretation of Aono.

Specifically, Aono indicates that a specific class of quinazolinones, i.e., those that are coupled to $-Z-Ar^1-(CO)-Ar^2$ wherein Z is a divalent group or a salt thereof; and Ar^1 and Ar^2 are independently an optionally substituted ring, may be useful for the treatment of cancers. Aono does not teach or suggest that *any* quinazolinone would have such utility.

Alternatively, the Office has cited Baxter for its description of class of substituted amide-quinazolinone compounds which can treat cellular proliferative diseases. However, Applicants respectfully assert that, for at least the reasons set forth above, Baxter does not rectify the deficiencies of the primary references. Baxter does not teach or suggest the methods claimed herein.

As such, none of the cited references, either alone or in combination, teaches or suggests that the quinazolinones used in the methods, as claimed herein, would have utility for the treatment of cellular proliferative disease. As the references do not teach or suggest the presently claimed invention,

Applicants assert that by suggesting that the cited art may be used to produce the methods of the presently claimed invention, the Examiner presents, in essence, an "obvious to experiment" or "obvious to try" standard for obviousness. The "obvious to try" standard has been thoroughly discredited. Indeed, an obviousness rejection is inappropriate, where the prior art [gives] either no indication of which parameters [are] critical or no direction as to which of many possible choices is likely to be successful" (quoting *In re O'Farrell*, 853 F.2d 894, 903, 7 USPQ2d 1673, 1681 [Fed. Cir. 1988], *Merck & Co., Inc. v. Biocraft Laboratories, Inc.*, 10 USPQ2d 1843, 1845 [Fed. Cir. 1989]).

There is no teaching in either of the cited references regarding methods for the treatment of cellular proliferation using the quinazolinones as claimed herein. There is simply nothing in the cited prior art that would provide one of ordinary skill in the art with the knowledge necessary to develop such methods (i.e., with the parameters and elements necessary to successfully conduct the presently claimed methods).


Therefore, Applicants submit that, for at least the reasons discussed above, the claimed invention is patentable over and not obvious in view of the cited references and respectfully request withdrawal of the rejections.

Conclusion

The Applicants respectfully maintain that all pending claims are in condition for allowance. Therefore, the Applicants respectfully request a Notice of Allowance for this Application from the Examiner. Should any unresolved issues remain, the Examiner is encouraged to contact the undersigned at the telephone number provided below.

Respectfully submitted,

Date: December 8, 2003

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